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PATENT APPLICATION
Docket No. 7678.350.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:		)
	Steven D. Jensen et al.	)
Serial No.:	09/710,181	) Art Unit) 1616
Filed:	November 10, 2000	)
Conf. No.:	4245	)
For:	COMPOSITIONS AND METHODS FOR WHITENING AND DESENSITIZING TEETH	)
Examiner:	Alton Nathaniel Pryor	)
Customer No.:	022913	)

REQUEST FOR PRE-APPEAL BRIEF CONFERENCE AND PANEL REVIEW

Mail Stop APPEAL
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the final Office Action of July 28, 2010, and concurrent with the filing of a Notice of Appeal, please consider the succinct, concise and focused set of arguments for which a pre-appeal brief conference and panel review is requested.

I. PRESENT INVENTION

The claims at issue recite dental bleaching and desensitizing compositions and associated methods of bleaching and desensitizing a person's teeth. The compositions generally include a dental bleaching agent, a relatively small amount of potassium nitrate (*e.g.*, about 0.01% to about 2% by weight), and a carrier comprising a solvent and tackifying agent in which the dental bleaching agent and the potassium nitrate are dispersed. The composition is also sufficiently non-abrasive so as to not externally abrade a tooth surface when applied thereto. Surprisingly, including the claimed limited amount of potassium nitrate has been shown to be more effective in reducing prospective tooth sensitivity caused by a dental bleaching agent as compared to when commonly used higher amounts of potassium nitrate are used. This is contrary to common sense and underscores the nonobviousness of the claimed invention.

II. THE CLAIMS COMPLY WITH THE WRITTEN DESCRIPTION REQUIREMENT UNDER 35 U.S.C. §112 PARAGRAPH 1

The Examiner commits clear error by rejecting claims 41-42, 44-48, 50-54, 56-63, 65-68, 70-87 and 91-93 as failing to comply with the written description requirement, particularly with respect to the phrases "the carrier being free of an amount of an abrasive that would externally abrade a tooth surface" and "does not externally abrade a tooth surface when applied thereto". These phrases closely match how the application describes the lack of abrasiveness of the disclosed bleaching compositions and are therefore fully supported.

When an application describes an invention in a manner that permits one of skill in the art to reasonably conclude that the inventor possessed the claimed invention, the written description requirement is satisfied (MPEP §2163). This possession may be shown in any number of ways. An Applicant is not required to describe every claim feature using the exact language in the application (*i.e.*, there is no *in haec verba* requirement) (MPEP § 2163). Rather, all that is required to satisfy the written description requirement is "reasonable clarity" (MPEP § 2163.02). Adequate description can be made through express, implicit, or even inherent disclosures in the application, including words, structures, figures, diagrams, and formulas (MPEP §§ 2163(I)).

Support in the originally filed application for the rejected phrases was specifically referenced in Amendment P, filed May 18, 2010. Examples of supporting disclosure in the application include: "the inventive compositions will preferably not include substantial quantities of an abrasive" (*see* p. 5, ln. 25-26); "[a]brasives only externally treat a tooth" (*see* p.

19, ln. 22); and "the compositions are preferably substantially free of abrasive" (*see* p. 5, ln. 20). In view of these teachings, one of skill in the art would easily recognize that the phrases "free of an amount of an abrasive that would externally abrade a tooth surface" and "does not externally abrade a tooth surface when applied thereto" mean exactly what they say – the claimed dental bleaching compositions either include no abrasive or an amount that is not sufficient to "externally abrade a tooth surface". A composition such as a toothpaste that includes sufficient abrasives to abrade a tooth surface is excluded from the claims.

III. THE CLAIMS ARE PATENTABLE OVER MCLAUGHLIN (6,108,850)

In rejecting the claims, the Examiner alleges that Example 4 of McLaughlin discloses the claimed compositions. Thus, to sustain the rejection over McLaughlin, the Examiner must establish that Example 4 of McLaughlin describes a toothpaste that includes every component recited in the claims *and* is non abrasive. The Examiner fails to meet this burden and by so doing commits clear error.

Example 4 of McLaughlin discloses a toothpaste but fails to list *any* of the following components: (1) solvent, (2) tackifying agent, and (3) abrasive (except for 1% titanium dioxide, which may act as an abrasive in combination with abrasives in the "paste carrier", which makes up 83.5% of the toothpaste composition). There are only two possible ways to analyze what is taught by Example 4: 1) ignore the "paste carrier" because we do not know what is in it and only consider the enumerated components or 2) interpret the "paste carrier" to include components normally found in toothpaste, including components disclosed in the McLaughlin specification.

No matter which approach is taken, Example 4 of McLaughlin fails to teach or suggest the combination of elements recited in the claims. If the Examiner ignores the paste carrier and only considers the enumerated components, then Example 4 fails to teach or suggest the claimed composition because it does not list any components that qualify as either a "solvent" or a "tackifying agent", much less both, as required by the claims. On the other hand, if the Examiner interprets the "paste carrier" to inherently include a solvent and tackifying agent, it necessarily follows that Example 4 describes an abrasive toothpaste composition. The Examiner, however, incongruously asserts that Example 4 includes a solvent and tackifying agent but is non abrasive, which contradicts the clear teachings in McLaughlin.

To support an assertion that Example 4 inherently includes a solvent and tackifying agent, the Examiner must rely on column 3, lines 50-61, of McLaughlin, which allegedly

discloses a "solvent" such as water, glycerin, sorbitol and polyethylene glycol and a "tackifying agent" such as carrageenan, xantham gum, and the like. Applicants emphasize that Example 4 fails to list *any* of water, glycerin, sorbitol, polyethylene glycol, carrageenan, or xantham gum. Nevertheless, assuming for the sake of argument that the "paste carrier" inherently includes a solvent and tackifying agent as unenumerated components, McLaughlin makes it perfectly clear that the paste carrier must also inherently include "an abrasive material".

> **When an abrasive material is included the vehicle may contain water, humectant, surfactant, and a thickener**. Examples of humectants are glycerin, sorbitol, and polyethylene glycol (molecular weight 200-1000). Both mixtures of humectants and single humectants can be employed in the composition of the invention. **Thickeners may be incorporated in the abrasive component** such as natural and synthetic gums such as carrageenan, xantham gum, sodium carboxymethyl cellulose, starch, polyvinylpyrrolidone, hydroxyethylpropylcellulose, hydroxybutyl methyl cellulose, hydroxypropyl methyl cellulose, and hydroxyethyl cellulose.

Col. 3, lines 50-61 (emphasis added). Therefore, if the paste carrier in Example 4 inherently includes a solvent and tackifying agent as asserted by the Examiner, the paste carrier also inherently includes an "abrasive material" in an amount so to clean teeth by abrasive action. To assert otherwise would render meaningless the teachings at col. 3, lines 38-49, which include a lengthy list of abrasives for the purpose of imparting abrasive activity to the toothpaste. It would be pointless for McLaughlin to include an abrasive within a toothpaste in an amount that failed to provide the intended purpose or principle of cleaning teeth by abrasive action.

In short, there are only two reasonable interpretations of Example 4, neither of which can be used to reject the claims. The first is that the term "paste carrier" is vague and fails to teach or suggest *anything* in particular, whether an abrasive, solvent or tackifying agent. Under this interpretation, McLaughlin fails to teach or suggest every element of the claimed composition because Example 4 fails to identify *any* solvent or tackifying agent, much less both. The second interpretation is that the "paste carrier" inherently contains components typically found in toothpastes, including an abrasive, which McLaughlin teaches is *always* present whenever a solvent and/or tackifying agent are included. Thus, if the "paste carrier" of Example 4 can be interpreted as the suggesting the use of a solvent *and* a tackifying agent, it also suggests including an abrasive material in an amount sufficient to clean teeth by abrasive action.

Indeed, Applicants have submitted evidence, including third party articles and statements made during prosecution of McLaughlin, that show that the toothpaste composition of Example 4

is abrasive. Moreover, statements made by the PTO and patentee during prosecution of McLaughlin confirm that McLaughlin discloses "an abrasive gel or scrubbing compound." In the Office Action dated April 8, 1999, the PTO stated that "[s]ince a *paste* is disclosed [in the cited art], an *abrasive* would be *inherent* in the formulation." *Id.* (emphasis added). This is clear evidence that the PTO understood the terms "paste" and "paste carrier" to inherently imply an abrasive composition in the context of McLaughlin. In response, patentee filed an Amendment dated July 12, 1999 and confirmed that McLaughlin discloses an abrasive composition. Patentee argued that the toothpaste composition in McLaughlin was patentable because the cited art did not teach "an *abrasive gel* or scrubbing compound" (Amendment, p. 8 (emphasis added)). That means that patentee considered his toothpaste composition to be "an abrasive gel or scrubbing compound", which confirms Applicants' position that Example 4 of McLaughlin is abrasive and therefore fails to teach or suggest the claimed dental bleaching and desensitizing compositions.

IV. THE CLAIMS ARE NOT OBVIOUS OVER THE CLAIMS OF U.S. PATENT NO. 6,306,370

Applicants performed a comparative study and found that bleaching compositions that included 0.5% potassium nitrate and 10.5% bleaching agent unexpectedly resulted in substantially lower oral sensitivity compared to compositions that included 3% potassium nitrate and either 10.5% or 15% bleaching agent. The comparative study is explained on pages 26-29 of the Application and was the subject of a previously filed declaration. Indeed, the Examiner "is in agreement" that the comparative study shows surprising and unexpected results but argues that the claims are not commensurate in scope with the comparative study because the claims recite ranges of about 10-30% bleaching agent and about 0.01-2% potassium nitrate.

The Examiner commits clear error by failing to properly compare and understand the relevant data. If using an amount of potassium nitrate (*e.g.*, 0.5%) within the narrowly tailored concentration range of about 0.01-2% together with a commonly used amount of bleaching agent (*e.g.*, 10%) was more effective in mitigating oral sensitivity that would otherwise be caused by the dental bleaching agent than when a larger amount of potassium nitrate was used (*i.e.*, 3%), it may reasonably be concluded that this trend would continue when larger (*e.g.*, up to about 30%) or smaller amounts of the dental bleaching agent are used. Similarly, because using 0.5% potassium nitrate unexpectedly resulted in reduced oral sensitivity compared to when either 3% or 0% is used, it is reasonable to conclude that amounts of potassium nitrate within narrowly

tailored ranges on either side of 0.5% would also provide greater desensitization compared to either 3% or 0% potassium nitrate.

Moreover, there is no rule or case law that requires Applicants to only claim the specific species used in the comparative study, and the Examiner cites to no rule or case law that would require this. On the contrary, MPEP § 716.02(d) states that "the nonobviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the probative value thereof". *In re Kollman*, 595 F.2d 48, 56 201 USPQ 193 (CCPA 1979); *In re Lindner*, 457 F.2d 506, 509, 173 USPQ 356, 359 (CCPA 1972); *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980). During prosecution, Applicants provided graphic evidence showing such a trend, and the instant claims only claim narrowly tailored ranged that were extrapolated from the test data and are therefore commensurate in scope with the comparative test.

V. CONCLUSION

In summary, Applicants submit that the claims satisfy 35 U.S.C. § 112, first paragraph, because the original language of the Application is sufficient to permit one skilled in the art to reasonably conclude that Applicants possessed the claimed invention. Second, McLaughlin does not teach or suggest a composition that is free of an amount of abrasives that would externally abrade a tooth surface. Third, the limitations of the claims are narrowly tailored and tightly centered around the comparative test data, which shows unexpected results when using a small quantity of potassium nitrate in combination with a dental bleaching agent, such that the claims are not obvious over the claims of U.S. Patent 6,306,370.

Dated this 28th day of October 2010.

Respectfully submitted,

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